exchanging, renting, or selling names and addresses of donors to, or members of, such organizations.".

(b) The amendment made by subsection (a) shall apply to taxable years ending after the date of the enactment of this Act.

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97TH CONGRESS
2D SESSION

S. 2948

To promote the development of nonanimal methods of research, experimentation, and testing, and to assure humane care of animals used in scientific research, experimentation, and testing.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 23 (legislative day, SEPTEMBER 8), 1982

Mr. DOLE introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To promote the development of nonanimal methods of research, experimentation, and testing, and to assure humane care of animals used in scientific research, experimentation, and testing.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as the "Humane Care and Development of Substitutes for Animals in Research Act".

FINDINGS

SEC. 2. The Congress finds that—

(1) the humane care of animals used in scientific research and testing should be assured as part of a respect for life, and the public interest in this matter should be respected;

(2) methods of testing that do not use animals have been developed which show promise of being faster, cheaper, and more accurate than traditional animal experiments for some purposes; and further opportunities exist for the development of these methods of testing;

(3) measures are needed to assure that where animal experimentation is necessary, treatment, care, and experimental methods and practices are such as to limit animal pain and distress to a minimum;

(4) institutional arrangements are needed to recognize the depth of public concern for protection of all life, and the expression of that concern in pressure for measures to minimize pain and distress of laboratory animals, and to improve self-regulating measures which reflect this concern; and

(5) measures which help to meet public concern for laboratory animal welfare are important in assuring that significant areas of science, in which animal experimentation is crucial, such as research benefiting human health, will continue to progress.

TITLE I—DEVELOPMENT OF IMPROVED RESEARCH AND TESTING METHODS

NONANIMAL TESTING METHODS

SEC. 101. (a) The Secretary of Health and Human Services (hereafter in this Act referred to as the "Secretary") is authorized to make awards—

(1) to sponsor research into, and development of, methods of research, experimentation, and testing which do not require the use of live animals, which reduce the numbers of live animals used, or which produce less pain and distress in such animals than methods currently in use; and

(2) to establish the validity and reliability of such methods for the purpose of replacing animal research and testing methods currently in use, where applicable.

(b) No award may be made under this section unless an application or proposal therefor has been assessed through applicable peer review procedures. Such application or proposal shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(c)(1) The Secretary shall designate an Advisory Panel to—

(A) provide advice concerning his responsibilities under this section and section 102;

(B) make such recommendations as it deems appropriate to the Secretary concerning specific opportunities or problems regarding research support of nonanimal testing; and

(C) design and recommend a system for insuring that any application or proposal meeting the requirements of this title will receive full consideration for funding by all appropriate programs of the Department of Health and Human Services, or for funding under this title from resources made available in accordance with subsection (d).

(2) Three years after the date of enactment of this Act, the Advisory Panel shall report to the Secretary on the impact of this Act on—

(A) industry costs;

(B) research;

(C) product prices; and

(D) progress made in lab accreditation.

This study shall not require or use additional Federal outlays.

(d) Funds for making awards under clauses (1) and (2) of subsection (a) shall be made available by the Secretary by allocation of adequate research resources within the Department of Health and Human Services.

ADDITIONAL RESPONSIBILITIES OF SECRETARY

SEC. 102. (a) The Secretary shall direct the National Institutes of Health, the Food and Drug Administration, and the National Toxicology Program, and shall consult with the Environmental Protection Agency and other appropriate regulatory and scientific research agencies to—

(1) promote the development of new, and the evaluation of existing, testing methods that do not require the use of animals and which will satisfy public health and safety concerns as well as regulatory requirements;

(2) promote the use of nonanimal methods of research, experimentation, and testing by seeking further cooperation in international regulatory research and development programs that would lead to more effective toxicologic data systems; and

(3) assure the efficient use of current and future research and test data involving animal use by enhancing the capabilities and the integration of data storage and retrieval systems.

(b) The Secretary shall direct the National Toxicology Program to significantly increase its resources for research and development on new methodologies and validation of nonanimal research and testing methods or computer models, which could be more rapid, less expensive, equally or more

reliable, and generate more useful toxicological and safety information.

(c) The Secretary shall submit a report to the Speaker of the House of Representatives and President of the Senate not later than two years after the date of enactment of this Act and biennially thereafter setting forth progress under this section, including new initiatives to reduce animal use and increased emphasis on development of new methodologies by the National Toxicology Program.

TITLE II—FEDERAL AWARD REQUIREMENTS

GENERAL REQUIREMENTS

SEC. 201. No Federal agency shall, after the effective date of this title, conduct within any of its own research entities, or approve any research entity for the receipt of a Federal award for the conduct of research, experimentation, or testing, involving the use of large numbers of animals unless—

(1) that research entity is accredited for such use in accordance with section 202; and

(2) that research entity has provided to the agency the assurances required under section 203.

ACCREDITATION

SEC. 202. (a) In order to be eligible to receive a Federal award for the conduct of research, experimentation, or testing, involving the use of large numbers of animals, a research

entity shall provide to the responsible Federal agency evidence that it is accredited as qualified to engage in such use by a recognized accrediting agency approved by the Secretary under subsection (b) of this section. The Secretary shall, by regulation, prescribe the form and manner in which such evidence shall be presented.

(b) For the purpose of accrediting entities for the conduct of research, experimentation, or testing, involving the use of large numbers of animals, the Secretary shall designate (and shall at least once each five years review the designation of) a private agency or agencies which the Secretary has determined to—

(1) have the demonstrated capability to ascertain the qualifications, background, and experience of research entities in the use of animals for such purposes;

(2) have established a system for the initial accreditation of research entities, including a mechanism for monitoring the correction of items of noncompliance;

(3) have established a system for the routine inspection, not less than once each three years, of laboratory animal facilities at any accredited research entity, such routine inspection to include a mechanism for monitoring the correction of items of noncompliance;

(4) have established a set of standards (A) for acceptable animal care, treatment, and use in experimental procedures, including appropriate and reasonable requirements with respect to handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperature, and exercise, and (B) with respect to other practices described in paragraphs (2) through (4) of section 301; and

(5) have established a mechanism for liaison with the institutional animal studies committees in accredited research entities, and for involvement of such committees in monitoring compliance with the accreditation standards.

(c) The standards established under subsection (b)(4) shall be designed to be eventually at least comparable to the best of current practices in animal care, treatment, and use in experimental procedures as specified in the "Guide for the Care and Use of Laboratory Animals" of the National Institutes of Health. Attainment of compliance with such standards by research entities shall be a prerequisite for full accreditation after a date which is ten years after the date of enactment of this Act, but accrediting agencies may, in accordance with regulations prescribed by the Secretary for the interim period, provisionally accredit research entities which demonstrate (1) satisfactory and continued progress toward

attainment of compliance with such standards, and (2) current practices which (A) comply with standards for animal care and treatment under the Animal Welfare Act of 1966 (7 U.S.C. 2131), and (B) include appropriate and reasonable requirements with respect to handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperature, and exercise, and other practices described in paragraphs (2) through (4) of section 301.

(d) In the event that no private agencies are found able to carry out the accrediting functions of this section, the Secretary shall, in cooperation with other Federal agency heads, establish within the Federal Government an accreditation mechanism to carry out such functions, to be fully supported by appropriate user fees.

ASSURANCES REQUIRED FROM RESEARCH ENTITIES

SEC. 203. (a) In order to be eligible to receive a Federal award for the conduct of research, experimentation, or testing, involving the use of large numbers of animals as required by section 201, a research entity shall provide to the responsible Federal agency a statement of assurances. Such statement shall be submitted at such time and in such manner and form as the agency may prescribe by regulation and shall demonstrate to the satisfaction of the agency—

(1) that the research entity has established an institutional animal studies committee (hereinafter in this

section referred to as the "committee") composed of not fewer than three members who collectively possess sufficient expertise to assess the appropriateness of animal use in experimental research and of which—

(A) at least one member is a doctor of veterinary medicine;

(B) at least one member is not affiliated with the research entity or parent organization and is primarily responsible for representing community concerns regarding the welfare of the animal subjects (such member shall have an appropriate research background and shall provide adequate assurances that he or she will not release any trade secrets of the research entity); and

(C) not more than three members are from the same administrative unit of the research entity;

(2)(A) that such committee—

(i) will meet regularly, and will have an appropriately constituted quorum for all formal actions;

(ii) will make inspections at least semiannually of all animal study areas and facilities of such research entity;

(iii) will review, as part of the inspection, research methods and practices in progress involving direct use of conscious animals, and the condition of research animals, for the purpose of evaluating these research methods and practices to ensure that animal pain and distress are minimized, and for compliance with experimental design of the original approved proposal, or with accepted standards for appropriate animal care, treatment, and use; and

(iv) will file with the responsible Federal agency certification that such inspections and reviews have taken place, along with reports of any violations of assurances given pursuant to this section, deficient conditions of animal care, treatment, or use, or deviations of research methods and practices from originally approved proposals in a manner adversely affecting animal welfare; and

(B) that such inspection certification will be signed by a majority of the members of the committee, and that minority views shall be included in the reports if any members so desire, except that, if either of the members designated in paragraph (1) (A) or (B) of this subsection do not sign

the majority report, they shall be particularly notified of the opportunity to file a minority report and given a reasonable time to do so;

(3) that the committee will maintain complete records of their inspection visits (including attendance of committee members), and other information pertinent to its activities, and that such records will be maintained for at least three years and will be available for inspection by any authorized Federal agency;

(4) that members of the committee will be encouraged individually to notify in writing the Animal and Plant Health Inspection Service of the Department of Agriculture, the responsible Federal agency, and the applicable accrediting agency (under section 202) of any unacceptable conditions of animal care, treatment, or use which have not been reported in writing by the committee as a whole and which have persisted despite notification to the research entity; and

(5) that the committee will establish courses or sessions available annually for scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the research entity, which provide instruction or training in (A) the humane practice of animal maintenance and experimentation, and (B) the concept, availability and use of research or testing

methods that minimize the use of animals or limit animal distress.

(b) In those cases where the sponsoring Federal agency determines that conditions of animal care, treatment, or use in a particular project have been persistently unacceptable despite notification to the research entity, that agency shall suspend or revoke Federal support for the project.

(c) Research entities shall inform their employees of the provisions of this title and shall instruct such employees to report to the animal studies committee any violations of such provisions, and no employees of such entities shall be discriminated against in their employment because such employees reported any such violation.

(d) The Secretary may waive the accreditation requirements under exceptional circumstances related to the needs for research results or special and unusual circumstances of the research entity.

COORDINATION

SEC. 204. The Secretary shall facilitate agency compliance with the requirements of this title through the establishment of a clearinghouse for information regarding appropriate methods and research models which are in compliance with such requirement.

DEFINITIONS

SEC. 205. For purposes of this title—

(1) the term "Federal agency" means an executive agency as such term is defined in section 105 of title 5, United States Code, and the term "responsible Federal agency" with respect to any research entity means the agency from which the research entity has received or may receive a Federal award for the conduct of research, experimentation, or testing, involving the use of animals;

(2) the term "Federal award for the conduct of research, experimentation, or testing, involving the use of animals" means any mechanism (grant, contract, cooperative agreement, or loan) under which Federal funds are provided to support the conduct of such research;

(3) the term "animal" refers to any living warm-blooded animal, that is, birds and mammals;

(4) the term "research entity" means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that is eligible to receive funds under a grant, cooperative agreement, loan, or contract from a Federal agency for the purpose of carrying out research, tests, or experiments on those animals;

(5) "direct use of conscious animals" means any use that involves more than momentary minor pain or discomfort, or any procedure except where the animal is anesthetized throughout the entire course of that procedure; and

(6) the term "large numbers of animals" means more than five hundred animals for rodent species, more than ten animals for nonrodent species, and one or more for nonhuman primates.

EFFECTIVE DATE

SEC. 206. The provisions of this title shall apply to any research entity that receives an award for the conduct of research, experimentation, or testing, involving the use of animals approved by any Federal agency on or after a date which is three years after the date of enactment of this Act, except that regulations implementing this title may be issued prior to that date.

TITLE III—SPECIAL PROCEDURES

FEDERAL AGENCY REVIEW OF AWARD PROPOSALS

SEC. 301. No Federal agency shall, after the effective date of this title, approve any research entity for the receipt of a Federal award for the conduct of research, experimentation, or testing, involving the direct use of conscious animals, unless the agency finds, as a result of its review of the scientific merit of the proposal, that the award proposal—

(1) includes a justification for anticipated animal distress in terms of the benefits of the research;

(2) includes, in any case involving the direct use of conscious animals, appropriate assurances that the services of a consulting doctor of veterinary medicine have been employed in the planning of such procedures;

(3) includes, in any case involving the direct use of conscious animals, appropriate provisions for assurances of the proper use of tranquilizers, analgesics, anesthetics, for control of paralytics, and for appropriate pre- and postsurgical medical and nursing care; and appropriate assurances that the withholding of tranquilizers, anesthesia, analgesia, or euthanasia when scientifically necessary shall continue for only the necessary period of time; and

(4) includes, except in cases of scientific necessity or other special circumstances as determined by the animal studies committee, assurances that no animal shall be used in more than one major operative procedure from which it is allowed to recover.

DEFINITIONS

SEC. 302. For the purposes of this title the terms "Federal agency", "responsible Federal agency", "research entity", "Federal award for the conduct of research, experimentation, or testing, involving the use of animals", "direct use of conscious animals", and "animals" have the meanings provided under section 205.

EFFECTIVE DATE

SEC. 303. The provisions of this title shall take effect one year after the date of enactment of this Act.

CONGRESSIONAL DISAPPROVAL

SEC. 304. No regulation promulgated under this Act shall take effect if disapproved by either House of Congress within sixty days of its proposal.

TITLE IV—EXEMPTION

SEC. 401. (a) Nothing in this Act shall be construed to apply to research, experimentation, or testing intended to improve animal nutrition, health, breeding, management, or production efficiency in horses, livestock, or poultry used or intended for use as food, including fish, or fiber, or for improving the quality or safety of food or fiber. Nothing in this Act shall be construed to apply to research, experimentation, or testing intended to improve wild animal conservation, propogation, or management.

(b) Nothing in this Act shall be construed to apply to specific experiments, research programs, or research facilities for which the accreditation, assurances, and award requirements of section 201, 202, 203, and 301 of this Act would present specific risks to national security or the safety of

manned space flight. Such exemption shall be effective upon certification by the responsible agency head to the Secretary that such risks are involved, along with reasons and justification. All such exemptions must be recertified annually and be available in an unclassified form for public review.

TITLE V—TERMINATION

SEC. 501. All authority conferred by this Act shall terminate ten years after enactment.

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AMENDMENT NO. 3630

Purpose: To modify the accreditation requirements and for other purposes.

IN THE SENATE OF THE UNITED STATES—97th Cong., 2d Sess.

S. 2948

To promote the development of nonanimal methods of research, experimentation, and testing, and to assure humane care of animals used in scientific research, experimentation, and testing.

October 1 (legislative day, September 8), 1982

Referred to the Committee on Labor and Human Resources and ordered to be printed

AMENDMENTS intended to be proposed by Mr. DOLE

Viz:

On page 3, line 22, strike out "(1)".

On page 3, line 24, strike out "(A)" and insert in lieu thereof "(1)".

On page 4, line 1, strike out "(B)" and insert in lieu thereof "(2)".

On page 4, line 5, strike out "(C)" and insert in lieu thereof "(3)".

On page 4, strike out lines 12 through 19.

On page 6, beginning with line 10 strike out through line 14 on page 9 and insert in lieu thereof the following:

"TITLE II—FEDERAL AWARD REQUIREMENTS

"GENERAL REQUIREMENTS

"SEC. 201. No Federal agency shall, after the effective date of this title, conduct within any of its own research entities, or approve any research entity for the receipt of a Federal award for the conduct of research, experimentation, or testing, involving the use of large numbers of animals unless that research entity has provided to the agency the assurances required under section 203 and has adopted a set of standards (A) for acceptable animal care, treatment, and use in experimental procedures, including appropriate and reasonable requirements with respect to handling, housing, feeding, watering, sanitation, ventilation, shelter from extremes of weather and temperature, and exercise, and (B) with respect to other practices described in paragraphs (2) through (4) of section 301.

"STANDARDS

"SEC. 202. (a) In order to be eligible to receive a Federal award for the conduct of research, experimentation, or testing, involving the use of large numbers of animals, a research entity shall provide to the responsible Federal agency evidence that it has met requirements to engage in such use as required by the Secretary under this title. The Secretary shall, by regulation, prescribe the form and manner in which such evidence shall be presented.

"(b)(1) Prior to the issuance of regulations and within one year of the date of enactment of this Act, the Secretary shall conduct a study to determine the possible economic impact of accreditation on biomedical and behavioral research facilities using live animals. The purpose of the study shall be to determine the costs of meeting standards comparable to those specified in the National Institute of Health 'Guide for the Care and Use of Laboratory Animals.'

"(2) After completion of the study provided for in paragraph (1) the Secretary shall issue regulations for implementing specific standards based on the results of the study. Such regulations shall also provide for waiver by the Secretary of accreditation requirements that cause an undue economic hardship on a research entity.".

On page 10, lines 11 and 12, strike out "shall have an appropriate research background and".

On page 15, line 7, strike out "five hundred" and insert in lieu thereof "one hundred".